



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/623,761

07/21/2003

John H. Laragh

55990/8

4847

31013 7590 01/10/2007
KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
1177 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

PETERSEN, CLARK D

ART UNIT

PAPER NUMBER

1657

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

3 MONTHS

01/10/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/623,761

Applicant(s)

LARAGH, JOHN H.

Examiner

Clark D. Petersen

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 14-17 are pending.

Claims 14-17 were examined on their merits.

Specification

The abstract of the disclosure is objected to because it expressly describes the proposed invention as "novel". Whether a proposed invention is novel or not is a determination of the US Patent and Trademark Office, and therefore the patent application cannot include such a descriptor before it has been examined. Please remove the word "novel" from the abstract. Correction is required. See MPEP § 608.01(b).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

Art Unit: 1657

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 14-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 25, and 26 of U.S. Patent No. 6,632,180. Although the conflicting claims are not identical, they are not patentably distinct from each other because every element of instant claims 14-17 is anticipated by claims 1, 25, and 26 of 6,632,180.

Instant claim 14 is identical in language to claim 1, steps A and B(I-iv). Because instant claim 14 does not include the subsequent steps of claim 1 in the cited patent, it

Art Unit: 1657

is broader in scope and therefore not identical, but every step of instant claim 14 is anticipated.

Instant claim 15 is identical in language to claim 25, steps A-D. Because instant claim 15 does not include the subsequent steps of claim 25 in the cited patent, it is broader in scope and therefore not identical, but every step of instant claim 15 is anticipated.

Instant claim 16 is identical in language to claim 26, steps A and B. Because instant claim 16 does not include the subsequent steps of claim 26 in the cited patent, it is broader in scope and therefore not identical, but every step of instant claim 16 is anticipated.

Instant claim 17 is identical in language to claim 26, steps A-D. Because instant claim 17 does not include the subsequent steps of claim 1 in the cited patent, it is broader in scope and therefore not identical, but every step of instant claim 17 is anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMahon (1978). McMahon teaches that some clinics routinely test patients for plasma

Art Unit: 1657

rennin activity, and that these patients fall into three categories: low, medium, and high rennin activity hypertensive patients. McMahon teaches that low renin patients can be administered a diuretic alone, i.e., a plasma volume-changing drug. Patients with higher plasma renin activity can be administered renin-blocking or -reducing drugs (see p. 3, for example). McMahon also teaches that it is standard practice, when one drug does not appear to be working, to add a second drug of a different type, i.e. if a diuretic is not working, add a renin-blocking agent, for example (see p. 4, for example). Lastly, McMahon teaches that one should treat the hypertension, not the renin level: because hypertension is a disease of high blood pressure, one must inherently monitor the blood pressure. McMahon also teaches that it is standard practice in treating hypertensive patients to titrate the drug to a proper dosage to eliminate the hypertension; determining proper dosage inherently involves measuring the blood pressure response to a given dosage.

A person of ordinary skill in the art at the time the invention was made would have been motivated to prescribe an anti-renin drug to a patient with medium to high PRA because McMahon teaches that such patients can be administered such drugs, and alternatively patients with low PRA should be administered diuretic drugs; additionally, McMahon teaches that it is standard practice to titrate dosage to achieve optimal amelioration of hypertensive symptoms, and because that doctors should treat the hypertension, it is inherent that blood pressure should be monitored because hypertension is a disease of high blood pressure.

Art Unit: 1657

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to prescribe a diuretic or renin-blocking drug based on PRA measurement, and to modulate dosages based on blood pressure response to drug administration.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMahon (1978) in view of Laragh (1998).

The teachings of McMahon are discussed above and applied as before.

McMahon does not expressly teach that a threshold level of plasma renin activity is 0.65 ng/ml/h.

Laragh teaches exactly that threshold as a guide for diagnosing primary aldosteronism (see p. 171S, col. 2, for example). Laragh teaches that finding a baseline plasma renin activity for every new patient greatly facilitates drug choice. The goal is to find the primary pressor mechanism: high renin indicates an anti-renin drug, while low renin indicates an antivolume drug. Laragh further teaches that the PRA test guides, simplifies, and hastens the selection of the right single drug for each patient (see p. 171S, col. 2, for example).

A person of ordinary skill in the art at the time the invention was made would have been motivated to treat a hypertensive with an anti-renin drug if their PRA was greater than 0.65 ng/ml/h because Laragh teaches that below that level the underlying pathology probably involves primary aldosteronism rather than renin-mediated hypertension.

Art Unit: 1657

Hence, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to prescribe a renin-blocking drug above 0.65 ng/ml/h PRA.

Conclusion

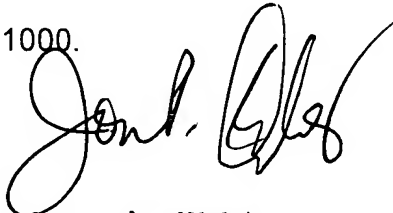
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clark D. Petersen whose telephone number is (571)272-5358. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571)272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDP
12/22/2006



Jon Weber
Supervisory Patent Examiner